BD MAX™ MRSA Assay
Premarket Notification K120138

JUL 5 2012

510(K) SUMMARY

June 1, 2012

BD MAX™ MRSA Assay

Submitted by: GeneOhm Sciences Canada Inc. (BD Diagnostics)
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Contact: Patricia Dionne, Ph.D.

Name of Device:

Trade Name: BD MAX™ MRSA Assay
Common Name: MRSA detection assay
Classification Name: System, Test, Genotypic Detection, resistant and non-resistant markers, *Staphylococcus* colonies

Predicate Device:

Performance/ Technology: BD GeneOhm™ MRSA ACP Assay (K093346)

Device Description:

Intended Use:

The BD MAX™ MRSA Assay performed on the BD MAX™ System is an automated qualitative *in vitro* diagnostic test for the direct detection of Methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of MRSA DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD MAX™ MRSA Assay is intended to aid in the prevention and control of MRSA infections in healthcare settings. It is not intended to diagnose, guide or monitor MRSA infections. A negative result does not preclude nasal colonization. Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

Test Description:

A nasal specimen is collected and transported to the laboratory using the recommended swab. The swab is placed in a BD MAX™ MRSA Sample Buffer Tube. The Sample Buffer Tube is vortexed to release cells from the swab into the buffer. The Sample Buffer Tube is placed onto the BD MAX™ System and the following automated procedures occur: the bacterial cells are lysed, DNA is extracted on magnetic beads and concentrated, then an aliquot of the eluted DNA is added to PCR reagents which contain the MRSA-specific primers used to amplify the genetic target, if present. The assay also

includes a Sample Processing Control (SPC). The Sample Processing Control is present in the Extraction Tube and undergoes the extraction, concentration and amplification steps to monitor for inhibitory substances as well as process inefficiency due to instrument or reagent failure. No operator intervention is necessary once the clinical sample and reagent strip are loaded into the BD MAX™ System. The BD MAX™ System automates sample lysis, DNA extraction and concentration, reagent rehydration, nucleic acid amplification and detection of the target nucleic acid sequence using real-time polymerase chain reaction (PCR). Amplified targets are detected with hydrolysis probes labeled with quenched fluorophores. The amplification, detection and interpretation of the signals are done automatically by the BD MAX™ System.

The BD MAX™ System uses a combination of lytic and extraction reagents to perform cell lysis and DNA extraction. Following enzymatic cell lysis at elevated temperature, the released nucleic acids are captured by magnetic affinity beads. The beads with the bound nucleic acids are washed and the nucleic acids are eluted by heat in Elution Buffer. Eluted DNA is neutralized with Neutralization Buffer and transferred to the Master Mix Tube to rehydrate PCR reagents. The reconstituted amplification reagent is dispensed into the BD MAX™ PCR Cartridge. Microvalves in the BD MAX™ PCR Cartridge are sealed by the system prior to initiating PCR to prevent evaporation and amplicon contamination.

The amplified DNA targets are detected using hydrolysis (TaqMan®) probes labeled at one end with a fluorescent reporter dye (fluorophore) and at the other end with a quencher moiety. Probes labeled with different fluorophores are used to detect MRSA and SPC amplicons in two different optical channels of the BD MAX™ System: MRSA amplicons are detected in the FAM channel and SPC amplicons are detected in the ROX channel. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the two optical channels used for the BD MAX™ MRSA Assay is directly proportional to the quantity of the corresponding probe that is hydrolyzed. The BD MAX™ System measures these signals at the end of each amplification cycle, and interprets the data to provide a result.

Substantial Equivalence:

The BD MAX™ MRSA Assay is substantially equivalent in performance to the BD GeneOhm™ MRSA ACP Assay (K093346).

Performance data:

Clinical performance characteristics of the BD MAX™ MRSA Assay were determined in a multi-site prospective investigational study. Four (4) investigational centers participated in the study.

The Comparative Reference Method consisted of direct culture complemented by enriched culture. Enriched culture analysis was completed for all specimens that were negative for MRSA by direct culture. Presumptive *S. aureus* colonies observed on selective (*S. aureus*) chromogenic media were subcultured onto Blood Agar (BA). Identification was confirmed with an agglutination test, while Methicillin-resistance was confirmed by Cefoxitin disk (30µg) diffusion susceptibility testing. Enrichment in Trypticase Soy Broth with 6.5% NaCl (TSB 6.5% NaCl) was completed in the event that Methicillin-resistant *S. aureus* was not confirmed by the initial direct culture method. Turbid TSB 6.5% NaCl broth was used to inoculate additional chromogenic media and BA plates; MRSA confirmation was performed as described above.

Results obtained are summarized in Tables 1 to 5.

Table 1: Results Obtained with the BD MAX™ MRSA Assay in Comparison to the Reference Method

All Sites		Reference Method		
		+	-	Total
BD MAX™ MRSA Assay	+	146	71	217
	-	11	1653	1664
	Total	157	1724	1881[1]

[1]The total number of specimens that were reference and PCR method compliant

Table 2: Performance Obtained using the BD MAX™ MRSA Assay in Comparison to the Reference Method

Clinical Sites	Prevalence[1]	Sensitivity with 95% CI[2]	Specificity with 95% CI[2]
Site 1	5.6% (28/496)	100.0% (28/28) (87.9%, 100.0%)	95.8% (435/454) (93.6%, 97.3%)
Site 2	4.6% (23/505)	91.3% (21/23) (73.2%, 97.6%)	96.5% (465/482) (94.4%, 97.8%)
Site 3	13.2% (55/417)	90.9% (50/55) (80.4%, 96.1%)	95.8% (346/361) (93.3%, 97.5%)
Site 4	10.9% (53/485)	92.2% (47/51) (81.5%, 96.9%)	95.3% (407/427) (92.9%, 96.9%)
Overall[3]	8.4% (159/1903)	93.0% (146/157) (87.9%, 96.0%)	95.9% (1653/1724) (94.8%, 96.7%)

[1] Prevalence based on reference method only
[2] CI: Confidence Intervals
[3] 1903 specimens were reference method compliant

Table 3: Results Obtained with the BD MAX™ MRSA Assay in Comparison to Direct Culture

All Sites		Direct Culture		
		+	-	Total
BD MAX™ MRSA Assay	+	133	84	217
	-	7	1657	1664
	Total	140	1741	1881

Table 4: Performance Obtained using the BD MAX™ MRSA Assay in Comparison to Direct Culture

Clinical Sites	Positive Agreement with 95% CI[1]	Negative Agreement with 95% CI[1]
Site 1	100.0% (22/22) (85.1%, 100.0%)	94.6% (435/460) (92.1%, 96.3%)
Site 2	95.5% (21/22) (78.2%, 99.2%)	96.5% (466/483) (94.4%, 97.8%)
Site 3	94.1% (48/51) (84.1%, 98.0%)	95.3% (348/365) (92.7%, 97.1%)
Site 4	93.3% (42/45) (82.1%, 97.7%)	94.2% (408/433) (91.6%, 96.1%)
Overall	95.0% (133/140) (90.0%, 97.6%)	95.2% (1657/1741) (94.1%, 96.1%)

[1] CI: Confidence Intervals

Table 5: Unresolved Rates

Clinical Sites	Initial Unresolved Rates with 95% CI[1]		Unresolved Rates After Repeat with 95% CI[1]	
Site 1	0.8% (4/484)	(0.3%, 2.1%)	0.0% (0/483)	(0.0%, 0.8%)
Site 2	0.0% (0/505)	(0.0%, 0.8%)	0.0% (0/505)	(0.0%, 0.8%)
Site 3	0.2% (1/416)	(0.0%, 1.3%)	0.0% (0/416)	(0.0%, 0.9%)
Site 4	1.0% (5/479)	(0.4%, 2.4%)	0.0% (0/478)	(0.0%, 0.8%)
Overall	0.5% (10/1884)[2]	(0.3%, 1.0%)	0.0% (0/1882)	(0.0%, 0.2%)

[1] CI: Confidence Intervals
[2] 1884 specimens were PCR method compliant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BD Diagnostics, Inc
c/o Mr. Raymond J. Boulé
Director, Regulatory Affairs
7 Loveton Circle, Mail Code 614
Sparks, MD 21152

JUL 5 2012

Re: K120138
Trade/Device Name: BD MAX™ MRSA Assay
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NQX, OOI
Dated: June 15, 2012
Received: June 18, 2012

Dear Mr. Boulé:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120138

Device Name: BD MAX™ MRSA Assay

Indication(s) for Use:

Intended Use

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Prescription Use XXX OR Over-The-Counter Use _____

(per 21 CFR §801, Subpart D) (per 21 CFR §801, Subpart C)

[Optional Format 01/02/1996]

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety (OIVD)

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